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10/530,737

04/08/2005

Josef Ehrenfreund

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11/19/2008

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EXAMINER

MANOHAR, MANU M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

11/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/530,737 | Applicant(s) EHRENFREUND ET AL. | |
| | Examiner MANU M. MANOHAR | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 24, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/2006, 04/08/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The status of the Claims

Claims 11- 18 are pending in the application. Original claims 11-18 were subjected to restriction and election of species. The details are below.

Election and Restriction

Applicant's reply on July 24, 2008 regarding election of Group I of claims 11-18 with traverse is acknowledged. The applicants elected the species, Formula 1, the compound Z202 from Table 16 from specification. The applicant states that the claims 11, 12 and 14-17 are readable on the elected species. The traversal is on the ground(s) that the search and examination of currently pending claims would not pose an undue burden on examiner. The compound and a method of using a compound are interrelated subject matter. The office action for requirement of restriction and election has not provided clear explanation about the lack of unity between compound and the method of using a compound. This is not found persuasive because of the rationale were presented in the restriction requirement mailed on June 25, 2008. Group I, claims 11- 17 are drawn to compounds and compositions and Group II, claim 18, drawn to method of use. The inventions listed as Groups I and II do not relate to a single general inventive concept. The compounds of the claims lack special structural element qualifying as special technical feature that defines a contribution over the prior art. The

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compounds contain tricyclic derivatives with 5 or 6 member heterocyclic rings (Het) and Het can be pyrrole or other derivative which does not result in a contribution over the prior art as stated in the previous office action. **Therefore the requirement is still deemed proper and is therefore made FINAL.** In response to applicant's election Group I (claims 11-17) Group II claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The claims 11, 12 and 14-17 which read on the elected species are only considered in the application.

Priority

The application is with a filing date of April 8, 2005. This application is a 371 of PCT/EPO3/11388 with filing date of Oct 14, 2003 which claims the benefit of United Kingdom 0224316 with the filing date of October 18, 2002 and examiner acknowledge the filing date of October 18, 2002. For this application the priority date is October 18, 2002.

Information Disclosure Statement

The information disclosure statement filed Dec 11, 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in

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the English language. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed April 08, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicant failed to provide copy of each cited non-patent literature publication.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 12 and 14-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

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claim 1 of the copending Application No. 11/996,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent Application 11/996,094 embrace the instant claims 11, 12 and 14-16. The compound described in the claims 11, 12 and 14-16 of the instant application encompasses the structure of the compound of formula (I) of claim 1 (where A subgroup is A37 of the copending application) of the copending Application No 11/996,094..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing attack on the infestation of microorganisms in the plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in

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the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

- 1) The breadth of claims: Claim 17 is directed to a method of preventing attack with infestation of microorganisms. This claim is too broad and it is not supported by the specification. It is known that infestation with microorganisms is diverse in nature and varied in the origin. Several different microbial infestations are there and each of them require different kind of prevention method and may require different compound or composition. It is clear to a person skilled in this art that each kind of infestation is distinct and varied in origin and distinct in the way of manifestation.
- 2) The nature of the invention: The invention is drawn to the compound containing pyrrolyl-pyrazolyl derivative having controlling activity to the microbial infestation to the plant. The instant claim is directed to preventing the infestation of plants with microorganisms.
- 3) The state of the prior art: The state of the art is high when the claims address preventing varied microbial infestation. Although there are number of publications describing methods of treating the infestation with compounds and compositions there is no evidence in the prior art that the instant composition would prevent the infestation. In the absence of further guidance, undue experimentation would be required by one skilled in the art to use the claimed method to prevent the microbial infestation.
- 4) The amount of direction provided by the inventor: There is minimal discussion in the specification that would indicate that the current invention prevents all the microbial infestation in the plants. The prevention of microbial infection in plants is a very broad

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claim. General guidance for preparing a composition with comprising the derivatives of pyrrolo-pyrazine as an active principle with a nonspecific adjuvants is given (Page 37-39 of the specification). However there are no specific directions about the formulation for the different doses for various microorganisms. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to practice the invention.

5) Predictability of the art: The art is unpredictable when the claim addresses preventing the infection. There are no evidences in the literature that state that any compound including the instant compound that would prevent all kind of infestation of plants. In the absence of further guidance, undue experimentation would be required by one skilled in the art to use the claimed method to prevent the infection of plant

6) The presence or absence of working examples: Applicant describes several experiments in the instant specification related to controlling the infection. These experiments illustrate the activity of the compound controlling a few fungicides. However the specific working examples are lacking for all the microbes that could infect the plants. There are no working examples of the specific formulation and administration for different kind of microbes.

7) The quantity of experimentation: One skilled in the art would be required to undertake undue experimentation to make and/or use the invention as claimed. First the subject matter of prevention is not established. It is not clear about methodology of identifying the subject that can be prevented from the infestation. Also there is a lack of methodology to establish that the subjects are prevented from the infection. Thus

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without undue experimentation one skilled in the art would not be able to practice this invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MANU MANOHAR
Examiner
Art Unit 4161

MM

/Rita J. Desai/
Primary Examiner, Art Unit 1625

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